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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,384	04/20/2006	Ehud Schwammenthal	U 016095-7	2944

140 7590 11/02/2007

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EXAMINER	
SWEET, THOMAS	
ART UNIT	PAPER NUMBER
3774	
MAIL DATE	DELIVERY MODE
11/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,384	SCHWAMMENTHAL ET AL.	
	Examiner	Art Unit	
	Thomas J. Sweet	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :07/17/2006, 10/13/2006, 01/05/2006, 06/21/2007, 08/13/2007.

DETAILED ACTION

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because the abstract is over 150 words.

Correction is required. See MPEP § 608.01(b).

Claim Objections

Claim 1 is objected to because of the following informalities:

Claim 1 recites the limitation "the plastic envelope" in the last line. There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which

it is most nearly connected, to make and/or use the invention. the word "forgers" does not have appear to have a basis in the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Regarding claim 1, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The word "forgers" makes no sense in the context of the claim. It appears to be a typo of the word "fingers".

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 5, 9 and 17-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims

of U.S. Patent No. 7201772. Although the conflicting claims are not identical, they are not patentably distinct from each other because the obvious combination of claims 1, 2, 5, 11 and metal as the attachment member (772). Regarding claims 2 and 20, claims 3 and 4 (772) combined with the normal anatomical dimensions of the aorta and annulus would result in the claimed dimensions. Regarding claim 3, met by claim 6 or 12 (772), Regarding claims 5 and 18, met by claim 9 (772).

Claims 1-3, 5, 13, 17-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10, 12 and 15-16 of copending Application No. 11/603912. Although the conflicting claims are not identical, they are not patentably distinct from each other because the obvious combination of claims 1, 2, 5, 16 (912) and metal as the attachment member meets claim 1. Regarding claims 2 and 20, claims 3 and 4 (912) combined with the normal anatomical dimensions of the aorta and annulus would result in the claimed dimensions. Regarding claim 3, met by claim 6 or 12 (912), Regarding claims 5 and 17-19, met by claims 7 and 8. Regarding claim 13, met by claim 15 (912).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 5-9, 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Bailey et al (US 6458153). Bailey et al discloses a prosthetic device for use in the treatment of aortic stenosis in the aortic valve of a patient's heart, said prosthetic device having a compressed state for transarterial delivery and being expandable to an expanded state for implantation, said prosthetic device comprising (such as shown in figs. 20A-20I):

an expandable metal base constructed so as to be implantable in the expanded state of the prosthetic device in the aortic annulus of the aortic valve (fig. 1); and

an inner envelope lining the inner surface of the metal base (11b, fig. 4);

characterized in that said inner envelope in the expanded state of the prosthetic device extends into the aorta and is of a diverging conical configuration (conical section in the area of 18), in which its diameter gradually increases from its proximal end within the aortic annulus to its distal end extending into the aorta, such as to produce, during systole, a non-turbulent blood flow into the aorta with pressure recovery at the distal end of the plastic envelope.

Regarding claim 3, proximal end of the inner envelope includes a short straight section of uniform diameter (at 20 in fig. 1) within said aortic annulus effective to avoid flow separation through said plastic envelope.

Regarding claims 5, 17 and 19, aortic valve of the patient's heart is of the type which includes a plurality of leaflets movable to open and closed positions (inherent native heart valve,

its not clear why specifics of the replaced valve are in the claim since the valve is not positively claimed nor could it be as a matter of non statutory 101 subject matter) and wherein said metal base includes two annular clamps engageable with the opposite sides of said leaflets in their open positions for clamping the metal base to said leaflets (at 22 and 18, clamping as shown in fig. 20G).

Regarding claims 6 and 18, each of said two annular clamps includes an annular array of forgers (as best understood fingers not forgers, elements 22 and 18 are fingers).

Regarding claim 7, wherein said metal base includes an annular array of bracing elements at the distal end of the prosthetic device engageable with the inner surface of the aorta for bracing the prosthetic device within the aorta (16).

Regarding claim 8, said bracing elements are integrally formed at one end with said annular array of fingers of one of said annular clamps (all one stent).

Regarding claim 9, said metal base, in the expanded state of the prosthetic device, extends to said distal end of the inner envelope, such that said inner envelope serves as a liner lining the inner surface of the metal base from said proximal end to said distal end of the prosthetic device (as shown by the dotted lines in fig. 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 4 and 20 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bailey et al. Bailey et al a prosthetic device as discussed above. However, Bailey et al does not expressly state the size of the stent, but the upper limits on aorta diameter and annulus diameter for and adult is the same as the upper ranges claimed. Based on proportions the length of fig. 1 is about the width at the aorta which is in the middle of the range for adult human. Additionally a change in size (or length) is prima facia obvious one is face as established by case law since there are some many reasons for change in size motivation is inherent. Therefore if the sizes are not considered inherent, it would have been obvious to one of ordinary skill in the art at the time the invention was made to size the stent of Bailey et al to the size of the human anatomy and vary the length as a matter of mere design consideration which is not patentably distinct from the prior art of Bailey et al.

Regarding claim 4, However, Bailey et al does not expressly state the length of the straight portion, but the annulus diameter for and adult is about 20 mm. Based on proportions the length of the straight portion in fig. 1 is least than about half the width at the annulus making it least than 10 mm. Additionally a change in size (or length) is prima facia obvious one is face as established by case law since there are some many reasons for change in size motivation is inherent. Therefore if the length are not considered inherent, it would have been obvious to one of ordinary skill in the art at the time the invention was made to size the straight portion of Bailey et al to a length of the straight portion from 2-10 mm as a matter of mere design consideration which is not patentably distinct from the prior art of Bailey et al.

Claims 1, 3, 5-8, and 10-16 are rejected under 35 U.S.C. 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hojeibane et al (US 20030236568).

Hojeibane et al discloses a prosthetic device (figs. 6B or 6C or 6G) fully capable of use in the treatment of aortic stenosis in the aortic valve of a patient's heart [0009], said prosthetic device having a compressed state for transarterial delivery and being expandable to an expanded state for implantation, said prosthetic device comprising:

an expandable metal base (101) constructed so as to be fully capable of being implantable in the expanded state of the prosthetic device in the aortic annulus of the aortic valve (fully capable since it can be used as a heart valve replacement, i.e. sized and shaped to fit) ; and

an inner envelope (102, inner and outer [0125]) lining the inner surface of the metal base;

characterized in that said inner envelope (102) in the expanded state (product by process limitation) of the prosthetic device is fully capable extends into the aorta and is of a diverging conical configuration (when mounted in the annulus the distal end is fully capable of opening wider than the annulus since the aorta is wider and the distal end if flexible, this is a product by process limitation for which Hojeibane et al is fully capable), in which its diameter gradually increases from its proximal end within the aortic annulus to its distal end extending into the aorta, such as to produce, during systole, a non-turbulent blood flow into the aorta with pressure recovery at the distal end of the plastic envelope.

Regarding claim 13, said metal base is configured and dimensioned to engage only the aortic annulus of the aortic valve when implanted therein (this is a product by process limitation for which Hojeibane et al is fully capable since metal base 101 need only be placed at expand to the annulus), said inner envelope extending into the aorta being of said diverging conical configuration during systole to permit forward blood flow therethrough, but collapsing during diastole to block reverse blood-flow therethrough (such as shown in fig. 6A).

Regarding claim 15, said inner envelope extending into the aorta includes a plurality of axially-extending reinforcing struts (620 or 630).

Regarding claim 16, wherein said reinforcing struts are hingedly (620 is connected to 101 by flexible 102 and 630 is a flexing member connected to 101) connected to said metal base.

Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al in view of Figulla et al (EP 1469797). Bailey et al a prosthetic device as discussed above. However, Bailey et al does not disclose metal base at the distal end of the prosthetic device carries a prosthetic valve controlling blood flow from the heart into the aorta. Figulla et al discloses another prosthetic device carrying a prosthetic valve on the metal base at the distal end of the prosthetic device for the purpose of controlling blood flow from the heart into the aorta. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the prosthetic valve on the metal base at the distal end of the prosthetic device as taught by Figulla et al on the distal end of the bailey et al stent in order to control blood flow from the heart into the aorta. Such a modification amounts to mere substitution of =one functionally equivalent valve for another within the art of heart valve prosthetics.

Regarding claim 11, said prosthetic valve includes a plurality of leaflets movable to open and closed positions (as shown in both references).

Regarding claim 12, prosthetic valve are integral with said inner envelope lining the inner surface of the metal base (as modified the valve would be connected to the distal end thereby forming one unit).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Several references are listed on the enclosed 892 form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 6:45am - 5:15pm, Tu-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thomas J Sweet
Examiner AU 3774